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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09 529,458	04 13 2000	JAY M. SHORT	DIVER1380-1	5257

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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06 07 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
<b>Advisory Action</b>	09/529,458	SHORT, JAY M.	
	Examiner Bronwen M. Loeb	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 May 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on 14 May 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 16-20 and 22-48.

Claim(s) withdrawn from consideration: \_\_\_\_\_

10/1/02 After Search Report is filed

Continuation of 3.

Applicant's reply has overcome the following rejection(s): The rejection of claims 16-20, 36, 37 and 42-47 under 35 USC §112, 1<sup>st</sup> lack of enablement; the rejection of claims 45-47 under 35 USC 12, 1<sup>st</sup> lack of enablement; the rejection; the rejection of claims 33-35 under 35 USC §112, 1<sup>st</sup> lack of written description (new matter); and the rejection of claims 36-48 under 35 USC §112, 2<sup>nd</sup>.

Continuation of 10. Other:

Claim 48 remains rejection under 35 USC §112, 1<sup>st</sup>. First, this claim still encompasses in vitro embodiments and Applicant's arguments, which are identical to the arguments presented in the amendment filed 20 August 2001, remain unpersuasive for overcoming this rejection for reasons of record. Second, the specification does not teach how to use a third molecule which affects the interaction of two unknown molecules, an embodiment encompassed by the claim language "at least one of a the first or second molecules is derived from a library" when the assay is performed in vitro.

The rejection of claims 16-20 and 22-35 under 35 USC §112, 2<sup>nd</sup> is maintained because the antecedent basis problem in claims 16 ("the response") and the indefiniteness in claim 22 ("a host cell" different from host cell recited in claim 16) were not addressed in the amendment. Correcting these two problems will overcome the rejection.

The art rejections are maintained as Applicant's arguments are not persuasive. Applicant argues: a prima facie case for obviousness has not been set forth; and Erickson et al is deficient. Applicant's argument regarding the prima facie case for obviousness is similar to that set forth in the amendment filed 20 August 2001 which was already addressed and found not persuasive in the rejection mailed 6 November 2001. Applicant argues that Erickson et al, the primary reference in the art rejections, is deficient. Applicant states that Erickson et al does teach or suggest a molecule from a library generated from a mixed population of organisms and does not teach identification of a third molecule responsible for inhibiting interaction between a first and second molecule wherein all three molecules are encoded by the same nucleic acid source. This is not persuasive as Erickson et al was cited for teaching identifying a third molecule as an inhibitor of an interaction between a first and second molecule wherein the third molecule is obtained from expression libraries, including genomic libraries. Generating a library from a mixed population of organisms is taught by both Stein et al and Short et al. Motivation to use the libraries of mixed populations of organisms in the method of Erickson et al comes both from the prior art (Horikoshi) and from the knowledge of one of ordinary skill in the art (see for instance Thompson et al, USP 5,824,485). Furthermore, while Erickson et al does not teach that all three interacting molecules are encoded by the same nucleic acid source, the pending claims are not restricted to that embodiment alone. Therefore, this argument is also not persuasive. Applicant also argues that Patanjali et al does not teach normalization as claimed. It is unclear what exactly Patanjali et al fails to disclose with respect to normalization of a genomic library. A flowchart of the steps for producing a normalized library is shown in Figure 1 of Patanjali et al which includes fractionating isolated nucleic acids, amplifying single stranded nucleic acids and cloning them into lambda gt10, an expression vector. Therefore, this argument is also not persuasive.

Please note the attached paper concerning the copy of papers originally filed.

*Remy Yucel*  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

09/529,458

The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

May 14, 2002

May 6, 2002

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The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS  
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will, **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-

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